

REMARKS

Claims 1-34 are pending. Claims 8-11, 24 and 34 are under examination. Claim 11 has been canceled. Claims 8-10, 24 and 34 have been amended. New claims 35-38 have been added. Support for the amendments and new claims can be found throughout the specification and the claims as filed. In particular, support for the amendment to claim 8 can be found, for example, in original claim 1, from which claim 8 depended. Support for the amendment to claims 24 and 34 can be found, for example, on page 26, lines 18-25. Support for new claims 35-38 can be found, for example, in original claims 24 and 34 and on page 26, lines 18-25. Accordingly, these amendments and new claims do not raise an issue of new matter and entry thereof is respectfully requested.

Regarding the New Restriction Requirement

Applicants acknowledge the new Restriction Requirement set forth in the Office Action mailed February 11, 2005. Applicants further affirm the election of Group II, claims 8-11, 24 and 34 and SEQ ID NO:14.

Regarding the Objections

The objection to the first paragraph of the specification is respectfully traversed. The first paragraph has been amended to delete spaces and update the priority claim and, accordingly, it is respectfully requested that this objection be withdrawn.

The objection to claims 8-11 for depending from non-elected claim 1 is respectfully traversed. Claim 8 has been amended to independent form and, accordingly, it is respectfully requested that this objection be withdrawn.

The objection to claims 8-11 for the term “encoding” is respectfully traversed. Claim 8 has been amended to delete the term “encoding” and to recite the term “encoded,” as suggested by the Examiner. Accordingly, it is respectfully requested that this objection be withdrawn.

The objection to claim 34 for the phrases “a Survivin binding domain” and “a cyclin-dependent kinase regulatory domain” is respectfully traversed. Claim 34 has been amended to recite structural characteristics of the domains by referencing the respective specific regions of SEQ ID NO:14. Accordingly, its respectfully requested that this objection be withdrawn.

Rejection Under 35 U.S.C. § 101

The rejection of claim 34 under 35 U.S.C. § 101 as allegedly directed to non-statutory subject matter is respectfully traversed. Claim 34 has been amended to recite “isolated” as suggested by the Examiner to distinguish the claimed chimeric protein from any naturally occurring chimeric protein. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Rejections Under 35 U.S.C. § 112, First Paragraph

The rejection of claims 8, 24 and 34 under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description is respectfully traversed. Applicants submit that the specification provides sufficient description and guidance for the claimed compositions.

Without addressing the merits of the rejection set forth in the Office Action, Applicants have nevertheless amended claims 8, 24 and 34 to recite an SBP polypeptide or SBP1 domain consisting of amino acids 1-91 of SEQ ID NO:14, wherein the polypeptide or domain binds Survivin; or an SBP polypeptide consisting of amino acids 85-125 of SEQ ID NO:14, wherein the polypeptide enhances cyclin B1/cdc2 kinase activity or the domain is a cyclin-dependent kinase regulatory domain, which are acknowledged in the Office Action to have sufficient written description, in order to further prosecution. Accordingly, Applicants respectfully request that this rejection be withdrawn.

The rejection of claim 8 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement is respectfully traversed. Applicants submit that the specification provides sufficient description and guidance to enable the claimed SBP1 polypeptide.

Without addressing the merits of the rejection set forth in the Office Action, Applicants have nevertheless amended claim 8 to recite an SBP polypeptide consisting of amino acids 1-91 of SEQ ID NO:14, wherein the polypeptide binds Survivin; or an SBP polypeptide consisting of amino acids 85-125 of SEQ ID NO:14, wherein the polypeptide enhances cyclin B1/cdc2 kinase activity, which are acknowledged in the Office Action to be enabled, in order to further prosecution. Accordingly, Applicants respectfully request that this rejection be withdrawn.

The rejection of claim 24 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement is respectfully traversed. Applicants submit that the specification provides sufficient description and guidance to enable the claimed therapeutic composition.

Without addressing the merits of the rejection set forth in the Office Action, Applicants have nevertheless amended claim 24 to recite a composition comprising a pharmaceutically acceptable carrier and a SBP polypeptide consisting of amino acids 1-91 of SEQ ID NO:14, wherein the polypeptide binds Survivin; or an SBP polypeptide consisting of amino acids 85-125 of SEQ ID NO:14, wherein the polypeptide enhances cyclin B1/cdc2 kinase activity, which are acknowledged in the Office Action to be enabled, in order to further prosecution. Accordingly, Applicants respectfully request that this rejection be withdrawn.

The rejection of claim 34 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement is respectfully traversed. Applicants submit that the specification provides sufficient description and guidance to enable the claimed chimeric protein.

Without addressing the merits of the rejection set forth in the Office Action, Applicants have nevertheless amended claim 34 to recite an isolated chimeric protein comprising a SBP1 domain selected from the group consisting of a Survivin-binding domain referenced as amino acids 1-91 of SEQ ID NO:14 and a cyclin-dependent kinase regulatory domain referenced as amino acids 85-125 of SEQ ID NO:14, which are acknowledged in the Office Action to be enabled for a heterologous protein comprising said SBP1 domains, in order to further prosecution. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Rejections Under 35 U.S.C. § 102

The rejection of claim 34 under 35 U.S.C. § 102(b) as allegedly anticipated by Tamm et al., *Cancer Res.* 58:5315-5320 (1998), is respectfully traversed. Applicants submit that the claimed chimeric protein is novel over Tamm et al.

Claim 34, as amended, is directed to an isolated chimeric protein comprising a SBP1 domain selected from the group consisting of a Survivin-binding domain referenced as amino acids 1-91 of SEQ ID NO:14 and a cyclin-dependent kinase regulatory domain referenced as amino acids 85-125 of SEQ ID NO:14. In contrast, Tamm et al. does not teach the claimed chimeric protein

comprising the specifically recited SBP1 domains. Furthermore, Applicants respectfully submit that, in contrast to the assertion in the Office Action, the Survivin-caspase-3/caspase-7 binding complexes described in Tamm et al. are not chimeric proteins, as claimed. Absent such a teaching, Tamm et al. cannot anticipate the claimed chimeric protein. Accordingly, Applicants respectfully request that this rejection be withdrawn.

The rejection of claim 34 under 35 U.S.C. § 102(b) as allegedly anticipated by Bourne et al., Cell 84:863-874 (1996), or Tsai et al., Nature 371:419-423 (1994), is respectfully traversed. Applicants submit that the claimed chimeric protein is novel over Bourne et al. or Tsai et al.

As discussed above, claim 34, as amended, is directed to an isolated chimeric protein comprising a SBP1 domain selected from the group consisting of a Survivin-binding domain referenced as amino acids 1-91 of SEQ ID NO:14 and a cyclin-dependent kinase regulatory domain referenced as amino acids 85-125 of SEQ ID NO:14. In contrast, neither Bourne et al. nor Tsai et al. teach the claimed chimeric protein comprising the specifically recited SBP1 domains. Moreover, Applicants respectfully submit that, in contrast to the assertion in the Office Action, the CksHs1-Cdk2 binding complex described in Bourne et al. and the p35 subunit bound to Cdk5 described in Tsai et al. are not chimeric proteins, as claimed. Absent such a teaching, neither of Bourne et al. nor Tsai et al. can anticipate the claimed chimeric protein. Accordingly, Applicants respectfully request that this rejection be withdrawn.

The rejection of claims 8-11 under 35 U.S.C. § 102(e) as allegedly anticipated by WO 2001/42451-A2 is respectfully traversed. Applicants submit that the claimed SBP polypeptides are novel over WO 2001/42451-A2.

Claim 8, as amended, is directed to an isolated SBP1 polypeptide, or functional fragment thereof, consisting of a polypeptide encoded by a nucleic acid molecule selected from the group consisting of a nucleic acid molecule encoding a polypeptide consisting of amino acids 1-91 of SEQ ID NO:14, wherein the polypeptide binds Survivin; and a nucleic acid molecule encoding a polypeptide consisting of amino acids 85-125 of SEQ ID NO:14, wherein the polypeptide enhances cyclin B1/cdc2 kinase activity, and wherein the SBP1 polypeptide or the functional fragment thereof binds Survivin or enhances cyclin B1/cdc2 kinase activity. In contrast, WO 2001/42451-A2 does not teach the claimed SBP1 polypeptide consisting of amino acids 1-91 or 85-125 of SEQ ID

NO:14. Absent such a teaching, WO 2001/42451-A2 cannot anticipate the claimed SBP1 polypeptides. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Rejections Under 35 U.S.C. § 103

The rejection of claim 24 under 35 U.S.C. § 103 as allegedly obvious over WO 2001/42451-A2 in view of Johnstone and Thorpe, Immunochemistry in Practice, 2nd ed., Blackwell Scientific Publications, Oxford, pp. 49-50 (1987), is respectfully traversed. Applicants submit that the claimed composition is unobvious over WO 2001/42451-A2, alone or in combination with Johnstone and Thorpe.

Claim 24, as amended, is directed to a composition comprising a pharmaceutically acceptable carrier and a SBP polypeptide consisting of amino acids 1-91 of SEQ ID NO:14, wherein said SBP polypeptide binds Survivin; or amino acids 85-125 of SEQ ID NO:14, wherein said SBP polypeptide enhances cyclin B1/cdc2 kinase activity. In contrast, WO 2001/42451-A2, alone or in combination with Johnstone and Thorpe, does not teach or suggest the claimed composition containing a SBP polypeptide consisting of amino acids 1-91 or 85-125 of SEQ ID NO:14 and a pharmaceutically acceptable carrier. Absent such a teaching or suggestion, it is respectfully submitted that the claimed composition is unobvious over WO 2001/42451-A2, alone or in combination with Johnstone and Thorpe. Accordingly, Applicants respectfully request that this rejection be withdrawn.

The rejection of claim 34 under 35 U.S.C. § 103 as allegedly obvious over WO 2001/42451-A2 in view of U.S. Patent No. 5,968,781, is respectfully traversed. Applicants submit that the claimed chimeric protein is unobvious over WO 2001/42451-A2, alone or in combination with U.S. Patent No. 5,968,781.

As discussed above, claim 34, as amended, is directed to an isolated chimeric protein comprising a SBP1 domain selected from the group consisting of a Survivin-binding domain referenced as amino acids 1-91 of SEQ ID NO:14 and a cyclin-dependent kinase regulatory domain referenced as amino acids 85-125 of SEQ ID NO:14. In contrast, WO 2001/42451-A2, alone or in combination with U.S. Patent No. 5,968,781, does not teach or suggest the claimed chimeric protein containing the specifically recited SBP1 domains consisting of amino acids 1-91 or 85-125 of SEQ

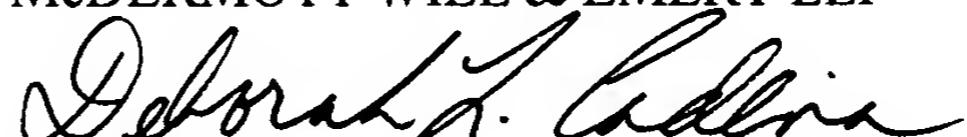
ID NO:14. Absent such a teaching or suggestion, it is respectfully submitted that the claimed chimeric protein is unobvious over WO 2001/42451-A2, alone or in combination with U.S. Patent No. 5,968,781. Accordingly, Applicants respectfully request that this rejection be withdrawn.

In light of the amendments and remarks herein, Applicants submit that the claims are now in condition for allowance and respectfully request a notice to this effect. The Examiner is invited to call the undersigned agent if there are any questions.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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